Exhibit G

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

December 5, 2022

Mr. David Y.Y. Light
Chief Executive Officer
Valisure, LLC
5 Science Park
New Haven, CT 06511-1966

Dear Mr. Light:

The U.S. Food and Drug Administration (FDA) inspected your drug contract testing laboratory, Valisure, LLC, FEI 3012063246, at 5 Science Park, New Haven, from May 26 to July 6, 2021.

FDA is concerned that Valisure, LLC is not aware of its violations of the drug supply chain security requirements while it owned ValisureRx. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA), places certain requirements on entities meeting the definition of trading partner. FDA acknowledges the sale of ValisureRx to Medly Health Inc. in April 2021. Until this sale, ValisureRx was a subsidiary of Valisure, LLC. ValisureRx was a licensed pharmacy and wholesale drug distributor, and therefore both a dispenser, as defined by section 581(3) of the FD&C Act, and a wholesale distributor, as defined by section 581(29) of the FD&C Act. ValisureRx was engaged in both wholesale distribution, as defined in section 503(e)(4) of the FD&C Act, and the dispensing of prescription drugs; and therefore was a trading partner under section 581(23) of the FD&C Act.

During FDA's inspection, FDA investigators examined records related to four (4) lots of product that were in Valisure, LLC's possession – including records from the purchase of the product, laboratory testing results, and records of the disposition of the product through a reverse distributor. FDA investigators observed that:

- Your firm failed to investigate suspect product;
- Your firm failed to make determinations of illegitimate product in coordination with the manufacturer; and
- Your firm failed to notify FDA and required trading partners of illegitimate product within 24 hours of such a determination.

During the inspection, FDA investigators observed that ValisureRx did not have systems in place to ensure compliance with the verification requirements of the FD&C Act (sections 582(c)(4)(A) & (B) and (d)(4)(A) & (B)), and in many instances, was not familiar with the requirements of the FD&C Act, as amended by the DSCSA, for wholesale distributors and dispensers.

Section 582(c)(4) and (d)(4) of the FD&C Act establishes the DSCSA's verification requirements for wholesale distributors and dispensers respectively and requires that such trading partners have systems in place to ensure compliance with the verification requirements (FD&C Act sections 582(c)(4)(A) & (B) and (d)(4)(A) & (B)). Among other things, Section 582 requires that product in the possession or control of a wholesale distributor or dispenser which is determined to be a suspect product[1] must be placed into quarantine and not processed further until a determination is made that the product is either cleared or illegitimate[2] (sections 582(c)(4)(A)(i)(I) and (d)(4)(A)(i)(I) of the FD&C Act). When a product is determined to be a suspect product, prompt investigations must be conducted in coordination with trading partners to determine whether the product is an illegitimate product (section 582(c)(4)(A)(i)(II) and (d)(4)(A)(ii) of the FD&C Act). In addition, the determination of whether a product is an illegitimate product must be made in coordination with the manufacturer (section 582(c)(4)(B)(i) and (d)(4)(B)(i) of the FD&C Act). Finally, if product is determined to be illegitimate product, the trading partner in possession or control of the product must notify FDA and certain trading partners of the illegitimate product within 24 hours of such a determination (section 582(c)(4)(B)(ii) and (d)(4)(B)(ii) of the FD&C Act).

In addition, FDA has observed that Valisure, LLC has never filed an annual report with the FDA as required by section 583(e)(2) of the FD&C Act. This provision requires wholesale distributors to report annually to the FDA each state by which the person is licensed and the name and address of each facility at which the person conducts business. FDA has no records, including in the CDER Direct Electronic Submissions Portal, that Valisure, LLC or ValisureRx reported to the Agency during the time it was engaged in wholesale distribution.

FDA recognizes that since the sale of ValisureRx, Valisure, LLC is no longer a licensed dispenser and that Valisure, LLC was not engaged in wholesale distribution at the time of the inspection. However, we emphasize that if your firm re-engages in such activities, you will be subject to the relevant requirements of the FD&C Act.

Please see the FDA guidance documents listed below for additional information about the DSCSA verification requirements and identifying suspect and illegitimate product under the DSCSA:

- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, Final Guidance, June 2021, https://www.fda.gov/media/88790/download

- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act, Draft Guidance for Industry, June 2021, https://www.fda.gov/media/111468/download

[1] *Suspect product* is defined in section 581(21) of the FD&C Act, in part, as "product for which there is reason to believe that such product appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

[2] *Illegitimate product* is defined in section 581(8) of the FD&C Act, in part, as "product for which credible evidence shows that the product appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans."

- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs, Draft Guidance for Industry, March 2022, https://www.fda.gov/media/117950/download

- Identifying Trading Partners Under the Drug Supply Chain Security Act, Draft Guidance for Industry, August 2017, https://www.fda.gov/media/106961/download

Additional Considerations

Based on the review of documents collected during the inspection, you provide contract testing services for drugs that have been placed into interstate commerce.

Your firm is subject to current good manufacturing practice (CGMP) requirements in that a drug is adulterated if the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of the drug do not meet CGMP as per section 501(a)(2)(B) of the FD&C Act. It is prohibited under the FD&C Act to cause the introduction or delivery for introduction into interstate commerce of an adulterated drug, per section 301(a). It is also prohibited to do any act with respect to a drug that is held for sale after shipment in interstate commerce, if such act results in the drug being adulterated, per section 301(k).

Our inspection found that you provide contract testing services for wholesale distributors and pharmacies that hold drugs for sale after shipment in interstate commerce, including your online pharmacy operation, ValisureRx. We acknowledge that you no longer perform pharmacy operations. You also conduct testing for drug manufacturers, and until recently, your website indicated that your offered services included a "certification process" whereby your testing concludes whether drugs you receive from a manufacturer are "ready for shipment."[3] We acknowledge your explanation in your response to the FDA Form 483 that "passing Valisure testing or obtaining a Valisure certification is not a requirement of drug manufacturing specifications nor FDA approval." However, we remain concerned that manufacturers may rely on your services in the future to perform contract testing to fulfill CGMP requirements, including those under section 21 CFR part 211.

We also are concerned that your distributor and pharmacy clients, despite not being obligated to perform the same type of release testing required of finished dosage form manufacturers under CGMP, may rely on your testing while a drug is held for sale, to inform their decision to further place a drug into interstate commerce. This letter summarizes scientific deficiencies in your test methods.

Methodological Deficiencies

During our inspection, our investigators observed methodological deficiencies including, but not limited to, the following.

[3] Valisure website as of April 13, 2022

1. Your firm failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of its test methods.

You did not demonstrate the analytical methods used to generate Certificates of Analysis (COAs) provided to your customers were suitable. For example,

- Your laboratory used the FDA's Gas Chromatography-Mass Spectrometry (GC-MS) method developed for the detection of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) in valsartan drug products.[4] However, you were using this method to detect additional impurities (e.g. (b) (4) , dimethylformamide (DMF), N-nitrosoethylisopropylamine (NEIPA), N-nitrosodiisopropylamine (NDIPA) and N-nitrosomethylethylamine (NMEA)), and were using this method for other drug products (e.g. (b) (4) , (b) (4) , (b) (4)) for which the method was not developed. Your firm failed to validate that this method can adequately detect these additional impurities in the drug products you analyzed. The FDA has previously communicated concerns about your inadequate data to support the use of FDA's GC-MS method for detecting impurities in drug products for which the method was not developed.[5]

- Your laboratory used the FDA's Liquid Chromatography High Resolution Mass Spectrometry (LC-HRMS) method developed for the detection of six nitrosamines in angiotensin II receptor blocker (ARB) drugs.[6] However, you used this method to additionally detect DMF and (b) (4) and to analyze other drug products including (b) (4) , (b) (4) , (b) (4) , and (b) (4) , for which the method had not been developed. You could not provide appropriate scientific studies and method validation results to support the use of this method for other drugs. The FDA has previously communicated concerns about the inadequate validation of your method for detection of NDMA in metformin.[7]

The verification of United States Pharmacopeia (USP) compendial methods was also inadequate. For example,

- Your laboratory used a modified version of the USP <467> GC-MS method for the detection of residual solvents, including (b) (4) , (b) (4) , and (b) (4) . You failed to

[4] FDA Analytical Method: FDA FY19-005-DPA-S "Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace" (01/28/2019), https://www.fda.gov/media/117843/download

[5] FDA has expressed concern with your nitrosamine analyses in previous correspondence, specifically with your use of FDA's GC-MS headspace method FY 19-005-DPA (appropriate for angiotensin II receptor blocker (ARBs)) for the analysis of ranitidine which causes the heat mediated degradation of the drug substance and artificially high levels of NDMA, https://www.regulations.gov/document/FDA-2019-P-4281-0008, "Final Response Letter from FDA CDER to Valisure, LLC", April 1, 2020, Footnote 43

[6] Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) Method for the Determination of Six Nitrosamine Impurities in ARB Drugs (05/21/2019), https://www.fda.gov/media/125478/download

[7] In the Citizen Petition Response, dated June 20, 2020, the FDA noted that Valisure did not perform sufficient studies to account for interfering substances such as DMF and could not meet the validation standard for specificity: https://www.regulations.gov/document/FDA-2020-P-0978-0009

provide adequate validation data for the modifications you made to the compendial. Likewise, liquid and gel (b) (4) drug products were analyzed using this unvalidated method without considering matrix effects.

- Your laboratory used a modified Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) method based on USP <232> and <233>. You did not provide adequate supportive validation data for the use of this modified method, including accuracy, spike and recovery, precision, and linearity per USP <233>.

- Your laboratory used a single High Performance Liquid Chromatography (HPLC) method for assay determination. You could not provide adequate supportive validation data for the use of this single method for assay determination of dextromethorphan hydrobromide, fexofenadine hydrochloride, and other drugs.

In addition, other analytical discrepancies were noted during the inspection and during the review of documents collected:

- Your methods, including GC-MS, ICP-MS, and HPLC, did not require a determination of system suitability prior to analysis, as per USP <621>.

- For nitrosamine determination by GC-MS, calibration standards were not run with the samples, and instead you relied on a calibration curve previous saved to the analytical system to quantify impurities. There was no established frequency for determining the calibration curve. Your laboratory manager stated that calibration may only be done when there is a column change or when instability is observed in the system.

- You did not provide stability data to support assay sample preparation by (b) (4) (b) (4) milling or compatibility data to support use of a (b) (4) um (b) (4) centrifuge filter during assay sample preparation.

- During FDA's review of HPLC chromatograms collected during the inspection, we determined that an incorrect baseline construction had been used for fexofenadine HCl lot # S200622 which resulted in inaccurate integration. Incorrect integration may lead to larger peak area and overestimation of assay and impurity concentrations for drugs.

In your response, you stated that your methods are accurate and reliable pursuant of International Organization for Standardization (ISO) procedures and failed to provide any supportive evidence or reports that your methods have been validated, verified, or suitable for use to support fulfillment of CGMP requirements, such as release decisions of drugs into interstate commerce.

Under CGMP, test methods used by manufacturers for drug product release decisions must be validated[8] for each drug product that will be tested using an analytical method. At a minimum, method validation experiments should include specificity, accuracy, precision (repeatability and intermediate precision), linearity, range, and limit of quantitation.

[8] See 21 CFR 211.165(e)

For FDA's current thinking about the validation of analytical methods see, FDA's *Analytical Procedures and Methods Validation for Drugs and Biologics Guidance for Industry* (July 2015): https://www.fda.gov/media/87801/download.

2. Your firm does not adequately address out-of-specification (OOS) test results.

You lack written procedures to govern the investigation of out of specification (OOS) results, including identification of adequate corrective action and preventive actions (CAPAs). For example, following the failure of an ICP-MS lead analysis for (b) (4) lot number (b) (4), you changed the tube digestion procedure and re-analyzed the sample without performing an OOS laboratory investigation or determining that the second digestion and re-analysis procedure were appropriate. Likewise, while your firm maintains a log of OOS results and corrective actions taken, your firm failed to provide adequate justification and evidence that these actions would be effective for resolving instrument, method, or other laboratory deviations observed.

Your laboratory manager stated that if the GC-MS method for nitrosamine impurities yields an OOS result, then the sample is analyzed by LC-MS. If the sample passes using the second LC-MS method, then the original OOS result is invalidated without an investigation. Your Chief Executive Officer confirmed this two-tier testing approach. You lack adequate justification for systematically invalidating OOS results when OOS results are found using your method. All test results, passing and failing, should be reported to your quality management system for review and provided to your customers for consideration when releasing drug products in interstate commerce.

For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production* for appropriately handling OOS and performing investigations at: https://www.fda.gov/media/71001/download

3. Your firm used instruments, apparatus, gauges, and/or recording devices that did not meet established specifications.

Your analytical instruments have not been adequately qualified for the testing performed. Equipment qualification had not been completed for the GC-MS, LC-HRMS, UPLC, and ICP-MS. For example, although you provided installation and operational qualification documents supplied by your ICP-MS instrument vendor, you did not provide sufficient evidence that the equipment was qualified for its intended purpose and could robustly perform the required operations.

In your response to the FDA Form 483, you stated that (b) (4) and routine maintenance is performed and that you maintain "objective evidence that [Valisure, LLC's] equipment can correctly perform all testing specified in the certifications [Valisure, LLC] provides." However, this information was not provided. In addition, your practice of assessing standard injections in advance of sample analysis is inadequate to demonstrate that the equipment can robustly perform the intended testing operations over the equipment lifetime.

4. Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records.

Your firm lacks controls to assure that analytical data is accurately processed, reviewed, and retained. While the software controlling your analytical equipment requires unique user accounts and passwords, your analysts log into the operating computers using a generic administrator account such as "Valisure" or "Valisure Lab." Controls are not in place to prevent the deletion of data from these administrator accounts.

Further, controls are not in place to ensure the accuracy of reported data results. When testing is completed, your analysts enter numeric values into a cloud database as the final result for the testing performed. Your firm could not provide associated procedures to review raw data, automated or manual data processing, or audit trails. You could not provide evidence of supervisory review of the testing performed.

Your response only addressed analyst accounts and access levels within the analytical software. You failed to address controls over the operating system which could allow for creation, modification, and deletion of data.

See FDA's guidance document *Data Integrity and Compliance With Drug CGMP* for guidance on establishing and following CGMP compliant data integrity practices at: https://www.fda.gov/files/drugs/published/Data-Integrity-and-Compliance-With-Current-Good-Manufacturing-Practice-Guidance-for-Industry.pdf and https://www.fda.gov/media/119267/download

Responsibilities of a Contract Testing Lab

As noted above, FDA documented that your website previously indicated the capability to test drugs in support of shipment release decisions, including for drug product manufacturers. Contract laboratories that perform testing for drug manufacturing facilities must meet applicable CGMP requirements. See FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements,* (November 2016) at https://www.fda.gov/media/86193/download.

Your Response to the FDA Form 483

In your response to the FDA Form 483 you stated that Valisure, LLC's testing is "only for informational and marketing purpose and not for any regulatory purpose." Additionally, you stated that your testing "is not subject to the cGMP standards set forth by FDA." You state that the purpose of your testing is to "broadly screen medicinal products" and that Valisure, LLC "does not typically run product-specific methodologies." Lastly, you stated, "Valisure's services are not intended for and not appropriate for any regulatory purpose." However, FDA is concerned that entities will use your test results for CGMP purposes.

If you intend to test drugs for purposes of fulfilling CGMP obligations, we recommend you perform a gap assessment to ensure you comply with CGMP. If you would like to meet with the

FDA to discuss minimal CGMP expectations, please contact CDER-OC-OMQ-Communications@fda.hhs.gov to schedule a meeting.

Valisure, LLC's Use of ISO Standard 17025

In your response to the FDA Form 483, you stated that Valisure, LLC's laboratory is accredited to the ISO 17025 standard[9] to ensure the testing conducted by Valisure, LLC is reliable and accurate. While there is value in accreditation to the ISO 17025 standard, FDA is concerned that potential clients who may use your services to support fulfillment of CGMP obligations may be unaware that ISO 17025 accreditation alone does not mean you are operating in compliance with CGMP requirements for the analytical testing of drugs subject to CGMP. Additionally, while you provided a copy of your ISO 17025 accreditation, based on the technical concerns described above, Valisure, LLC appears to deviate significantly from the ISO 17025 standard.

Conclusion

The deficiencies cited in this letter are not intended to be an all-inclusive list of those that exist at your facility. You are responsible for investigating and determining the causes of any deficiencies and for preventing their recurrence.

This letter notifies you of our findings and provides you an opportunity to address them. After you receive this letter, please respond to this office in writing within 30 working days. Specify what you have done to address any deficiencies identified above and to prevent their recurrence.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3012063246.

Sincerely,

/s/

Jill P. Furman
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

[9] ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories"